United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
ADAMA IRVITA N.V. 3120 HIGHWOODS BLVD., SUITE 100 RALEIGH, NC 27604	3125 - Propiconazole Chemical # and Name: 122101 Propiconazole	12-Apr-2017 GENERIC ID # GDCI-122101-1705

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Applicator Exposure Data Requirements (Conventional Chemical)								
875.1700	Product Use Information **(13, 15)**	N				C,X,BB,A	TEP	12	
875.2700	Product Use Information **(12, 15)**	N				C,X,BB,A	TEP	12	
	Post-Application Exposure Data Requirements (Conventional Chemical)								
875.2100	Foliar dislodgeable residue dissipation **(2, 14)**	Y				C,X,BB,A	TEP	24	
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.1075	Fish acute toxicity test, freshwater and marine **(14, 23, 33)**	N				C,X,BB,A	TGAI	12	
850.1400	Fish early-life stage toxicity test **(14, 16, 33)**	N				C,X,BB,A	TGAI	12	
850.2100	Avian acute oral toxicity test **(14, 18)**	N				C,X,BB,A	TGAI	12	
850.2300	Avian reproduction test **(14, 17)**	N				C,X,BB,A	TGAI	24	

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company

13. Phone Number

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	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.3040	Field testing for pollinators **(1, 3, 14, 21, 32)**	Y				C,X,BB,A	TEP	24	
835.1110	Activated sludge sorption isotherm **(15, 30)**	N				C,X,BB,A	TGAI	12	
835.3110	Ready biodegradability **(15, 29)**	N				C,X,BB,A	TGAI	12	
835.3220	Porous pot test **(15, 28)**	N				C,X,BB,A	TGAI	12	
835.3240	Simulation Test-Aerobic Sewage Treatment-Activated Sludge **(15, 27)**	N				C,X,BB,A	TGAI	12	
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals **(15, 26)**	N				C,X,BB,A	TGAI	12	
850.3300	Modified Activated Sludge, Respiration Inhibition Test **(15, 25)**	N				C,X,BB,A	TGAI	12	
SS-1155	Residues in Pollen and Nectar/Field Residue Analysis **(4, 14, 31)**	Y				C,X,BB,A	TEP	24	

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4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
SS-1311	Honey bee adult acute oral toxicity **(6, 14)**	N				C,X,BB,A	TGAI	12	
SS-1312	Honey bee larvae acute oral toxicity **(9, 14)**	N				C,X,BB,A	TGAI	12	
SS-1313	Honey bee adult chronic oral toxicity **(7, 14, 32)**	Y				C,X,BB,A	TGAI	12	
SS-1314	Honey bee larvae chronic oral toxicity **(8, 14, 32)**	Y				C,X,BB,A	TGAI	12	
SS-1319	Semi-field testing for pollinators (tunnel or colony feeding studies) **(5, 14, 22, 24, 32)**	Y				C,X,BB,A	TGAI or TEP	24	
SS850.1000	Chronic Estuarine/Marine Sediment Testing **(10, 15, 19, 32)**	Y				C,X,BB,A	TGAI	24	
SS850.1000	Chronic Freshwater Sediment Testing **(11, 15, 20, 32)**	Y				C,X,BB,A	TGAI	24	

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 3125 - Propiconazole

DCI Number: GDCI-122101-1705

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

Use Categories Key:

A - Terrestrial food crop

C - Terrestrial nonfood crop

X - Materials preservatives

BB - Wood preservatives

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

1	USEPA. 2012c. Field Testing for Pollinators. Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
2	Turf grass transferable residue dissipation data are required to assess the residential use of propiconazole on turf.
3	Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
4	Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.
5	Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
6	Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en
7	Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295
8	Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf
9	Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
10	This study must be conducted using Leptocheirus plumulosus.
11	This study must be conducted for both Hyalella Azteca and Chironomus dilutes.
12	This data requirement is triggered by the antimicrobial wood preservative use sites.
13	This data requirement is triggered by the antimicrobial paints and stains use sites.
14	These data are required for conventional use sites.
15	These data are required for antimicrobial use sites.
16	Study must be conducted using saltwater fish species.

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17 Study must be conducted using mallard duck.

18 Study must be conducted using a passerine species. The OCSPP 850.2100 guideline currently recommends the submission of a protocol for EPA review prior to initiation of tests conducted with passerine species. Data submitters are encouraged to consider the recommendations contained in relevant EPA reference documents (i.e., OCSPP 850.2100, EFED Guidance for Reviewing OCSPP 850.2100 Avian Oral Toxicity Studies Conducted with Passerine Birds, EFED Guidance for Use when Regurgitation is Observed in Avian Acute Toxicity Studies with Passerine Species) when preparing test protocols. A protocol does not need to be submitted to EPA for review prior to test initiation if it reflects these recommendations. If a data submitter elects to submit a protocol to EPA, in order to facilitate the review process, any aspects of a proposed study design that differ from this guidance should be noted and accompanied by a descriptive rationale which addresses why they are not expected to adversely impact the quality of the resulting study.

19 Studies are to be conducted using ORD Study Methods, as specified. The ORD Study Methods can be accessed via EPA's Online Library System. The study methods for Hyallela and Chironomus are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30003SBA.txt and the study methods for Lepto. are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30002GRK.txt Registrants must use the test method: "Leptocheirus plumulosus." In: USEPA 2001. "Method for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod Leptocheirus plumulosus." Doc. No. EPA 600/R-0l/020

20 Studies are to be conducted using ORD Study Methods, as specified. The ORD Study Methods can be accessed via EPA's Online Library System. The study methods for Hyallela and Chironomus are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30003SBA.txt and the study methods for Lepto. are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30002GRK.txt Registrants must use the test method: "Hyalella azteca 42-d Test for Measuring the Effects of Sediment-associated Contaminants on Survival, Growth, and Reproduction." In: USEPA 2000. "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates." Doc. No. EPA 600/R-99/064.

21 See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0004; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.

22 Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of either a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (Apis mellifera L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.

23 For freshwater species, study must be conducted with fathead minnow.

24 For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616.

25 EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0021. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en. The results of the Activated Sludge Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests is/are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant must conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge, or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then the (i) Biodegradation in Activated Sludge, or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot study is required.

26 EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0036 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

27 EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0034 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

28 EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0024 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

29 EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0017 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test

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30 EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0003.

31 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.
- Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under.
- Consideration of the attractiveness of the selected crop to pollinators.
- Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time.
- Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators.
- Consideration of the market proportion of the selected target crop(s).

32 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

33 850.1400, saltwater fish early life stage study may be waived if an acceptable 850.1075, freshwater fish acute toxicity study with a fathead minnow is submitted. In lieu of a saltwater fish early life stage study (850.1400), an acute to chronic ratio (ACR) will be calculated using data from an acceptable freshwater fish acute toxicity study (850.1075 with a fathead minnow).

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DATA CALL-IN RESPONSE

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EPA FORM 6300-4

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4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
74054-3				N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company

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